

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418
<p>This Document Relates to:</p> <p>IRWIN CHAIKEN, <i>et al.</i>, Plaintiffs, v. BRISTOL-MYERS SQUIBB, <i>et al.</i>, Defendants.</p>	<p>Civ. Action No.: 13- 4518(FLW)</p> <p>OPINION</p>

WOLFSON, District Judge:

This matter is a member case to the Multi-District Litigation ("MDL") entitled, *In Re: Plavix Marketing, Sales Practices and Products Liability Litigation*, which is assigned to the Undersigned. Plaintiff Barbara Thrope ("Plaintiff" or "Thrope") brings the instant suit against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that she suffered injuries as a result of Defendants' design, development,

manufacture, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Complaint asserts various California state and common law claims against Defendants, including Failure-to-Warn, Defective Design, Manufacturing Defect and Negligence. Before the Court is Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under California law.

BACKGROUND¹

I. Plavix

Plavix is a drug that inhibits blood platelets from forming clots. The drug was initially approved by the United States Food and Drug Administration ("FDA") for use as monotherapy, *i.e.*, taken without another drug, in patients with recent heart attack, stroke, including Transient Ischemic Attack ("TIA"), or diagnosed peripheral arterial disease. See Defs. Statement, ¶ 2.

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, it is well known that Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, its labeling included certain

¹ The following facts are not in dispute unless otherwise noted. And, the Court will only recount facts that are relevant to the instant motion.

information on that risk. When Plaintiff was using Plavix in 2011, the drug label provided:

CONTRAINDICATIONS

Active Bleeding

Plavix is contraindicated in patients with active pathological bleeding such a peptic ulcer or intracranial hemorrhage.

* * *

WARNINGS AND PRECAUTIONS

General Risk of Bleeding

Thienopyridines, including Plavix, increase the risk of bleeding. If a patient is to undergo surgery and an antiplatelet effect is not desired, discontinue Plavix five days prior to surgery.

Patients with Recent Transient Ischemic Attack (TIA) or Stroke

In patients with recent TIA or stroke who are at high risk for recurrent ischemic events, the combination of aspirin and Plavix has not been shown to be more effective than Plavix alone, but the combination has been shown to increase major bleeding.

* * *

ADVERSE REACTIONS

Bleeding:

CAPRIE (Plavix vs. Aspirin)

In CAPRIE, gastro-intestinal hemorrhage occurred at rate of 2.0% in those taking Plavix, vs. 2.7% in those taking aspirin; bleeding requiring hospitalization occurred in 0.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for Plavix (clopidogrel bisulfate) compared to 0.5% for aspirin.

* * *

PATIENT COUNSELING SECTION

Bleeding

Inform patients that they:

- will bruise and bleed more easily
- will take longer than usual to stop bleeding
- should report any unanticipated, prolonged, or excessive bleeding, or blood in their stool or urine.

Defs' Facts, ¶ 4 (citing May 2011 Plavix label as published in the 2012 Physicians' Desk Reference at pp. 824-25).

II. Plaintiff's Medical History

Hopkins is an 83 year-old woman from Spring Valley, California. In September 2011, Plaintiff was hospitalized and treated for TIA, or the lack of blood flow to the brain, which can lead to a stroke. See Dr. Eva Leonard's Dep., T16:7-19:22; T23:14-24:19. Plaintiff, who was a smoker, had a history of atherosclerosis, chronic hypertension. *Id.* at T53:11-55:1.

At the time Plaintiff was hospitalized, Plaintiff's neurologist, Dr. Amirhassan Bahreman, recommended that Plaintiff be placed on Plavix, because she was allergic to aspirin and/or aspirin-intolerant. See Dr. Bahreman's Dep., T39:17-40:3; T44:3-15; T50:16-T51:10; T113:20-114:4. When Plaintiff was discharged on September 28, 2011, her primary care physician,

Dr. Eva Leonard, prescribed Plavix to Plaintiff, until November 2011, when Plaintiff suffered GI bleeding.

Due to the gastrointestinal bleeding allegedly resulting from taking Plavix, Plaintiff brings the instant suit against Defendants asserting product liability related causes of action, under California state law, for defective design, manufacturing defect, failure to warn and negligence.

III. Testimony of Plaintiff's Doctors

The parties questioned both Drs. Bahreman and Leonard at their deposition. At his deposition, Dr. Bahreman testified regarding his decision to prescribe Plavix to Plaintiff. The doctor testified that at the time Plaintiff was hospitalized, based on the fact that Plaintiff might have been intolerant of aspirin and other factors, he decided that Plavix was the best option for Plaintiff. See Dr. Bahreman's Dep., T50:20-T51:10. Important to his decision, Dr. Bahreman recognized that Plaintiff had outstanding GI issues, and he determined that taking aspirin would exacerbate those conditions. *Id.* at T51:22-T52:23.

Moreover, Dr. Bahreman testified that he was aware that Plavix has common side effects, such as GI bleeding, and that aspirin, in his medical opinion, has more GI side effects. *Id.* at T55:21-T56:5; T59:1-2. The doctor went on to testify that he is aware of the studies involving Plavix, such as the MATCH

trial and the CAPRIE trial. See *Id.* at T60:23-T61:8. And, armed with that knowledge, Dr. Bahreman explained that Plavix, as an antiplatelet, would carry a bleeding risk. *Id.* at T114:25-T115:9. Specifically regarding Plaintiff's risk of taking Plavix, Dr. Bahreman testified:

Q: Now, this is a patient [Plaintiff] who you - your recommendation was that she be on a single antiplatelet therapy, correct?

A: Yes. That's correct.

Q: And you believed that for this patient in her clinical situation, the benefits of being on antiplatelet therapy outweighed its risks, correct?

A: Absolutely.

Q: Specifically included GI bleeding risk, correct?

A: That's correct.

* * *

Q: And do you believe that based on the information that you've seen today about the patient that this was a justifiable prescription of Plavix for her under the circumstances?

A: At that time, it was justifiable.

Q: And is there anything that you've seen today that makes you think that it wasn't justifiable?

A: Well, no. I don't think so. You know, when you have a patient with a history of GI bleed, history of documented GI bleed, not intolerance, GI bleed, using those medications always needs an extra caution. So I would say if I had this patient today, definitely I would have to look to the data on the documents or records much more in depth. And - but - again, this is the matter of the risk and benefit ratio.

Id. at T118:18-T120:10.

Because Dr. Bahreman treated Plaintiff in the context of Plaintiff's hospitalization, the doctor made the initial decision to administer Plavix to Plaintiff. Importantly, however, Dr. Bahreman explained that it would be the decision of Plaintiff's primary care physician, Dr. Leonard, to prescribe any particular medication upon discharge. *Id.* at T112:12-18. Indeed, Dr. Bahreman insisted that his role is solely to provide consult and input, but it is up to Dr. Leonard to make a final decision regarding certain prescriptions, including the decision to prescribe Plavix to Plaintiff. *Id.* at T112:20-23. In fact, to be clear, when Plaintiff suffered GI bleeding in November 2011, she was on Plavix that was prescribed by Dr. Leonard.

Similar to Dr. Bahreman, Dr. Leonard testified that, based on Plaintiff's medical condition, she had no reservations – even knowing the risks posed by Plavix – about prescribing Plavix to Plaintiff:

Q. [Reading from Plaintiff's discharge form] [I]t also says, "But we shall give the Plavix an opportunity at this time, understanding that the patient does have a bleeding risk." Do you see where I – the –

A. Yes.

Q. Oka. And what does that sentence mean? Why is it there, do you think?

A. Well, apparently, at this hospitalization, one has to [weigh] the risk and the benefits.

Q. Okay.

A. She has risks for potential bleeding from her past history, but when you have symptoms of a stroke or a TIA, it's like a red flag. You want to prevent a stroke. A stroke can kill somebody. But a stomach ulcer is not necessarily going to kill somebody. So it's sort of weighing the risks and the benefits

Id. at T27:14-T28:21. Indeed, Dr. Leonard acknowledged that bleeding is the "biggest" risk for taking Plavix. *Id.* at T36:9-13.²

² The depositions of Drs. Bahreman and Leonard were taken by the parties before the instant motion for summary judgment was filed. After the deposition of Dr. Bahreman, Plaintiff's counsel engaged in *ex parte* conversations with the doctor for the purposes of opposing Defendants' summary judgment motion. Indeed, after those communications took place, Dr. Bahreman submitted a declaration, which was attached as an exhibit to Plaintiff's opposition brief in this matter, seeking to clarify certain testimony that he had given during his deposition.

As Defendants pointed out, a previous Order, entered by the Magistrate Judge early in this litigation, disallowed counsel to have any *ex parte* communications regarding liability issues with the treating physicians of any of the plaintiffs in the MDL, with no exception for post-deposition communications. See Order dated April 14, 2011. Indeed, the Special Discovery Master extended the Magistrate Judge's Order uniformly to all cases nationwide.

Because Dr. Bahreman's declaration made it apparent that Plaintiff had discussed liability issues with the doctor, Defendant sought a ruling from the Special Master to forbid such *ex parte* contacts. However, the Special Discovery Master declined to limit *ex parte* communications which take place after a deposition. Thereafter, Defendants moved before this Court to sustain certain objections to the Special Master's ruling. As to that motion, I partially reversed the Special Master's decision; I held that counsel may not have *ex parte* communications with plaintiffs' treating physicians, including post deposition, except that counsel may contact a treating

IV. Procedural History

This action, originally filed in Illinois state court, was removed by Defendants to the United States District Court for the Northern District of Illinois. Once removed, the matter was transferred to this MDL litigation by the MDL Panel. Defendants filed the instant motion for summary judgment on August 8, 2017, and Plaintiff has opposed the motion.³ The Court held oral argument on September 12, 2017, wherein the parties' counsel appeared, and the Court reserved decision on the record.

DISCUSSION

I. Summary Judgment

Summary Judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, (1986) (citing Fed. R. Civ. P.

physician at the close of discovery and after the resolution of a summary judgment motion.

On this motion, Defendants object to Plaintiff using Dr. Bahreman's declaration in her opposition, and ask this Court to disregard the declaration based on the fact that it was obtained by improper *ex parte* communications and pursuant to the sham affidavit doctrine. Because I find that even considering Dr. Bahreman's declaration, summary judgment is appropriate, I need not address those arguments.

³ The parties agree that California law applies to Plaintiff's claims.

56(c)). A factual dispute is genuine only if there is "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party," and it is material only if it has the ability to "affect the outcome of the suit under governing law." *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment. *Anderson*, 477 U.S. at 248. "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255); see also *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, (1986); *Curley v. Klem*, 298 F.3d 271, 276-77 (3d Cir. 2002).

The party moving for summary judgment has the initial burden of showing the basis for its motion. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "If the moving party will bear the burden of persuasion at trial, that party must support its motion with credible evidence . . . that would entitle it to a directed verdict if not controverted at trial." *Id.* at 331 (emphasis and citation omitted). On the other hand, if the

burden of persuasion at trial would be on the nonmoving party, the party moving for summary judgment may satisfy Rule 56's burden of production by either (1) "submit[ting] affirmative evidence that negates an essential element of the nonmoving party's claim" or (2) demonstrating "that the nonmoving party's evidence is insufficient to establish an essential element of the nonmoving party's claim." *Id.* (citations omitted). Once the movant adequately supports its motion pursuant to Rule 56(c), the burden shifts to the nonmoving party to "go beyond the pleadings and by her own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (quotations omitted); see also *Matsushita*, 475 U.S. at 587; *Ridgewood Bd. of Ed. v. Stokley*, 172 F.3d 238, 252 (3d Cir. 1999). In deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. *Anderson*, 477 U.S. at 249. Credibility determinations are the province of the factfinder. *Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992).

There can be "no genuine issue as to any material fact," however, if a party fails "to make a showing sufficient to establish the existence of an element essential to that party's

case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322-23. "[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id.* at 323; *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 n.5 (3d Cir. 1992).

II. Failure to Warn

With respect to Plaintiff's failure to warn claim, Defendants argue that the learned intermediary doctrine precludes Plaintiff from suing them because the doctrine excuses drug manufacturers from warning Plaintiff, individually, when these manufacturers have properly and adequately warned the prescribing physicians regarding Plavix's risks. Indeed, the sole basis for Defendants' summary judgment motion on Plaintiff's failure to warn claim is the defense under the learned intermediary doctrine; notably, on this motion, Defendants do not challenge Plaintiff's position that Plavix's label is inadequate, and thus, this issue is not before me.

The California Supreme Court has held that manufacturers of prescription drugs can be held strictly liable for failure to warn of knowable risks. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1069 (1988). Indeed, a manufacturer of prescription drugs owes to the medical profession the duty of providing adequate warnings if it knows, or has reason to know, of any dangerous

side effects of its drugs. *Carlin v. The Superior Court of Sutter County*, 13 Cal. 4th 1104, 1112-13 (1996). "The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Id.* at 1112. In short, under California law, a plaintiff asserting a claim based on a manufacturer's failure to warn must establish that (1) a warning was absent or inadequate, and (2) the absence or inadequacy caused the plaintiff's injury. *See Plummer v. Lederle Labs.*, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law).

However, a pharmaceutical manufacturer does not have a duty to warn the ultimate consumers of a drug's potential dangers if adequate warning has been given to physicians; this is the so called learned intermediary doctrine. *Carlin*, 13 Cal. 4th at 1116. Importantly, "in the case of prescription drugs, the duty to warn runs to the physician, not to the patient." *Id.* (emphasis omitted); *see Martin v. Merck & Co., Inc.*, No. 05-750, 2005 U.S. Dist. LEXIS 41232, at *9-10 (E.D. Cal. Aug. 15, 2005) (noting that the learned intermediary doctrine is a defense to a cognizable cause of action).

The California Court of Appeals explained the rationale behind the learned intermediary doctrine as follows:

(1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

Carmichael v. Reitz, 17 Cal. App. 3d 958, 989 (1971) (citation omitted).

Accordingly, "a manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." See *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 990-91 (C.D. Cal. 2001). It follows that any failure to warn cannot be considered a proximate cause of a subsequent injury to the consumer if the treating physician was fully aware of the dangers that would have been included in an alternative warning. *Id.*

To overcome the learned intermediary doctrine on a summary judgment motion, the plaintiff must present evidence to show that the "non-disclosed risk was sufficiently high that it would have changed the treating [or prescriber] physician's decision

to prescribe the product for the plaintiff." *Motus*, 196 F. Supp. 2d at 996 (quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 815 (5th Cir. 1992) (discussing a plaintiff who suffered seizures after taking Accutane and failed to prove that an inadequate warning caused her injuries because the risk of seizures from Accutane is so low that it could not have affected the doctor's decision to prescribe the medication)) (citing *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991) (explaining it is unlikely that doctor would have changed his mind to implant artificial heart valves where the risk undisclosed by the warnings - a .03 percent per annum rate of failure due to soot pockets -- was minimal and "plaintiff failed to present any specific evidence that this . . . risk would have changed [the doctor's] decision"); *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981) (explaining that plaintiff could not prove that manufacturer's failure to warn that its flu vaccine could cause Guillian-Barre Syndrome resulted in her contracting the syndrome, because even if manufacturer had provided adequate warnings, a reasonable physician still would have administered the flu vaccine "despite the slight risk" that plaintiff would contract GBS)). But see *Georges v. Novartis Pharmaceuticals Corp.*, No. 06-5207, 2012 U.S. Dist. LEXIS 189174, at *15-17 (C.D. Cal. Nov. 2, 2012) (citing several district court cases involving Aredia and Zometa

denying summary judgment where the plaintiff provided evidence that the physician would have changed a prescription or treatment procedure); *In re Aredia & Zometa Products Liab. Litig.*, No. 06-1760, 2009 U.S. Dist. LEXIS 72098, at *7 (M.D. Tenn. Aug. 13, 2009) ("[I]t is sufficient for Plaintiff to survive summary judgment to show that one of [plaintiff's] treating physicians . . . would have behaved differently.") (applying California law). Importantly, in the case of prescription drugs, the duty to warn runs to the *prescribing* physician. *Carlin*, 13 Cal. 4th at 1116; *Motus*, 196 F. Supp. 2d at 990.

Indeed, nationally, it is well-settled that in prescription drug failure-to-warn cases, courts apply this doctrine. See, e.g., *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (concluding that summary judgment was proper where the "doctor provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed [the drug] . . . Pursuant to Georgia's learned intermediary doctrine, this assertion severs any potential chain of causation"); *Ebel v. Eli Lilly & Co.*, 536 F.Supp. 2d 767 (S.D. Tex. 2008) (granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa's suicide-related risks that an adequate warning would have provided and that plaintiff had

presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd*, 321 Fed. App'x 350 (5th Cir. 2009) (per curiam); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 U.S. Dist. LEXIS 12500, at *10, *18 (E.D. La. Feb. 20, 2008) (granting summary judgment to defendant because plaintiff had failed to show (1) that defendant did not adequately warn the physician of a risk associated with the drug that was not otherwise known to the physician and (2) that the "failure to warn the physician was both a cause in fact and the proximate cause of the plaintiffs' injury"), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, 314 Fed. App'x 701 (5th Cir. 2009) (per curiam).

Here, there is no dispute that both Drs. Bahreman and Leonard testified – at their deposition – that even considering the bleeding risks and the additional warnings, they would have prescribed Plavix to Plaintiff in light of various medical factors in connection with Plaintiff's condition, particularly the fact that Plaintiff might have been intolerant of aspirin. On this motion, however, Plaintiff's opposition focuses solely on a declaration Dr. Bahreman supplied to Plaintiff's counsel after the doctor's deposition and after Defendants filed their summary judgment motion. Plaintiff points out that Dr. Bahreman indicated in his declaration that after having reviewed the Chan

Study in greater detail,⁴ the doctor opined that Plavix should have included a warning about the risk of recurrent bleeding ulcers associated with Plavix and a placebo over aspirin and a proton pump inhibitor. Plaintiff argues that, based on that information, Dr. Bahreman would have changed his decision regarding Plaintiff's Plavix prescription. In that regard, Plaintiff could only survive summary judgement if Dr. Bahreman's post-deposition declaration is sufficient to raise a triable issue on summary judgment. I do not so find for the reasons below.

First, as a threshold matter, the parties do not center their arguments on the following dispositive issue: whether Dr. Bahreman was the physician who prescribed Plavix to Plaintiff during the relevant time period that led to Plaintiff's GI bleeding in November 2011. To be clear, in the case of prescription drugs, under California law, the duty to warn only applies to the *prescribing* physician. *Carlin*, 13 Cal. 4th at 1116; *Motus*, 196 F. Supp. 2d at 990. As explained above, Dr. Bahreman was the neurologist who treated Plaintiff during her

⁴ Generally, the Chan Study, entitled *Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding*, concluded Plavix is not as safe or superior on the stomach than aspirin plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec), in light of the Study's findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. See *Begley v. Bristol-Myers Squibb Co.*, No. 06-6051, 2009 U.S. Dist. LEXIS 121058, at *11-12 (D.N.J. Dec. 30, 2009).

September 2011 hospitalization, and although Dr. Bahreman administered the initial dose of Plavix to Plaintiff during that time, with regard to the decision of prescribing Plavix to Plaintiff, Dr. Bahreman explicitly testified that it would be the determination of Plaintiff's primary care physician, Dr. Leonard, to place Plaintiff on any prescription after Plaintiff was discharged:

Q: And whose decision would it be - when in a situation like this where Dr. Leonard's patient is in the hospital and she is asking you for a consult, and then you give you neurological consult and then the patient is discharged, whose decision is it to prescribe particular medications on discharge.

A: Primary care physician.

Q: Okay.

A: Dr. Leonard.

Q: You give your input, and then it's up to her to make the decision?

A: Absolutely.

Dr. Bahreman's Dep., T112:12-25. Thus, Dr. Bahreman's testimony in this regard is unequivocal - that in Plaintiff's circumstance, Dr. Leonard was the prescribing physician.

While Dr. Leonard testified that she rarely initiates any prescription when a patient is being treated by a specialist, she, nonetheless, made the decision to prescribe Plavix to Plaintiff at the time Plaintiff was discharged from the hospital. See Dr. Leonard's Dep., T56:20-23. Indeed,

Plaintiff's discharge summary makes it clear that Dr. Leonard made the independent medical decision to prescribe Plavix. See Discharge Summary, p. 1. In that Summary, Dr. Leonard noted that Dr. Bahreman indicated that he would like Plaintiff to be placed on Plavix, and that Dr. Leonard, herself, concurred with that determination, because Plaintiff was, *inter alia*, intolerant of aspirin. See *id.* Ultimately, at the time Plaintiff was discharged from her September 2011 hospitalization, Dr. Leonard faxed Plaintiff's prescriptions, including Plavix, to a pharmacy. See *id.* Subsequently, and most importantly, Plaintiff suffered GI bleeding in November 2011, when Plaintiff was on the prescription given by Dr. Leonard.

In that regard, based on the testimony of both doctors and documentary evidence, I find that although Dr. Leonard consulted with Dr. Bahreman and other doctors regarding Plaintiff's condition and on which type of medications should be prescribed to Plaintiff, Dr. Leonard was the final decision-maker, or the prescribing physician, who ultimately determined that the benefits of placing Plaintiff on Plavix far outweighed the bleeding risks that she posed. Thus, for the purposes of applying the learned intermediary doctrine, the relevant inquiry should be focused on whether Dr. Leonard was sufficiently warned by Defendants regarding the risks of Plavix, and whether Dr. Leonard would, in any event, have prescribed Plavix to Plaintiff

in light of additional warnings proposed by Plaintiff. Indeed, as to both of these questions, Dr. Leonard testified in the affirmative. Accordingly, based on this reason alone, I reject Plaintiff's 11th-hour submission of Dr. Bahreman's declaration obtained *after* his deposition, for the purposes of defeating summary judgment.

Next, even considering Dr. Bahreman's declaration, I still find summary judgment appropriate. To defeat summary judgment, Plaintiff attempts to use Dr. Bahreman's declaration to clarify his testimony regarding the Chan study during his deposition. On that topic, Dr. Bahreman, at first, testified that he did not remember reviewing such a study in 2011, or that he was aware of the conclusions of the Chan study. See Dr. Bahreman's Dep., T90:10-T91:9. However, the doctor, at his deposition, was read the results of the study, and when questioned whether knowing those results would change his mind about administering Plavix to Plaintiff, he responded:

A: . . . It might be this study confirm also this general kind of agreement that we have as neurologist just having intolerance is not enough to disqualify patients from aspirin or Plavix. So - but [the Chang study] is another . . . study which confirmed our general opinion, if I'm not mistaken.

* * *

Q: Okay. If you had been aware of such a study existing, would you consider this in any way relevant to your clinical practice?

A: At this point, no. Of course, every study, everything, there is a point for all of us, of course we are learning, of course. But if you think that I am going to change my opinion about Plavix at this point, no, I won't.

Again, just know that intolerance topics, intolerance, bleeding ulcers in the patient who had a history of bleeding in the past, those are the things that we are putting them in the equation. There are a lot of patients having no problem whatsoever, GI problems, with the Plavix or aspirin. So it doesn't change our opinion about using either of them. In the future or the like currently.

If we have a patient with a GI bleed, we have to be cautious. We know that. We have to be cautious for both [aspirin and Plavix.] And if I have an allergy - a patient with allergy, definitely my threshold for using Plavix is much lower than having intolerance about aspirin.

Id. at T92:10-15; T96:14-T97:16.

In his post-deposition declaration, Dr. Bahreman states that "[a]t the time Ms. Thorpe was prescribed Plavix, it was my belief that Plavix was not more dangerous than aspirin for patients that had a documented gastrointestinal intolerance of aspirin." Dr. Bahreman's Dec., ¶ 6. Dr. Bahreman further states that he was not aware of the Chan study or its conclusions that patients with a history of bleeding ulcers were much less likely to suffer recurrent bleeding when taking aspirin plus a PPI rather than Plavix alone. *Id.* at ¶ 8. But, significantly, the doctor explains that it was his belief that had Plavix labeling included the Chan study, he would have "shared" that information, and Plaintiff "would not have been prescribed Plavix." *Id.* at ¶ 9. Thus, placed in that context,

it appears that Dr. Bahreman is declaring that he would have shared the information regarding the Chan study presumably with Dr. Leonard, and he surmises, *post hoc*, that Plaintiff would not have been given Plavix – by Dr. Leonard – to treat her medical condition. Indeed, that statement is consistent with Dr. Bahreman's prior testimony that he only provided input to Dr. Leonard as to the types of prescription Plaintiff should be given, not that he was the ultimate prescriber. It follows that because Dr. Bahreman was not the prescriber that led to Plaintiff's bleeding episode, his statement regarding whether a different warning would have changed his input or consultation with the prescriber, cannot raise a genuine issue of material fact on the learned intermediary analysis.

Instead, as I have already explained, Dr. Leonard's medical determinations are relevant in this regard, particularly her opinions regarding the Chang study, the basis upon which Plaintiff relies to defeat summary judgment. At Dr. Leonard's deposition, counsel questioned whether it was the doctor's opinion, in the context of the Chan study, that "there was a higher rate of ulcer bleeding with clopidogrel [Plavix] than with the aspirin and the esomeprazole [PPI] group." Dr. Leonard's Dep., T44:18-23. Criticizing the design of the study, Dr. Leonard responded, "No, because it is not comparing apples to apples. I mean, it seems to me that one should have the

clopidogrel with the esomeprazole, rather than a placebo to compare." *Id.* at T25:25-T26:3. Moreover, when asked whether patients with ulcer bleeding should not be given Plavix instead of aspirin, Dr. Leonard explained:

A: Well, its saying that patients who have had bleeding from aspirin in the past - which is the group they studied, which doesn't apply to my patient [Plaintiff], but - they should not be given the clopidogrel is what it's saying.

It doesn't explain - I mean, it needs more testing is what it is. Would it make any difference? That's why I'm saying, I don't know if there are other studies that show that aspirin versus clopidogrel with and without a PPI has any differences. I just don't know that data.

Id. at T45:18-T46:3. More importantly, when further asked whether the Chan study would have changed her prescribing decision in November 2011, Dr. Leonard stressed: "No, because this didn't apply to my patient." *Id.* at T47:10-11.

In short, fatal to Plaintiff's position, Dr. Leonard testified unequivocally that the Chan study was irrelevant to her prescribing decision because that study did not apply to Plaintiff's medical circumstances, and because its study design did not compare "apples to apples." See Dr. Leonard's Dep., T47:7-11, T44:25-T45:3.⁵ Hence, Plaintiff's submission of Dr.

⁵ Because Dr. Leonard testified that the Chan study would not have changed her decision, I need not discuss in detail Plaintiff's argument that the conclusions made by the Chan study squarely apply in Plaintiff's circumstances. But, I note that the Chan study only involved patients who presented with active ulcer bleeding, whereas, Plaintiff was known to have a past

Bahreman's declaration fails to defeat summary judgment, because Dr. Bahreman's speculative statement regarding what Dr. Leonard would have concluded is insufficient to raise any doubt as to Dr. Leonard's testimony, such that an issue of fact would exist.

In sum, Plaintiff has failed to point to any evidence to meet her burden of proving causation. Plaintiff must show, on this motion, a changed prescription decision; however, Dr. Leonard has testified that she knew full well that Plavix increases bleeding risk and that Plaintiff was at a high risk of bleeding given her past history of ulcers and other risk factors. In light of that unambiguous testimony, Plaintiff simply has not produced any evidence to controvert Dr. Leonard's statements; put differently, Plaintiff has not shown that a different prescription decision would have been made if Dr. Leonard were presented with additional information about Plavix's bleeding risk, *i.e.*, the Chan study. Indeed, Dr. Leonard addressed the Chan study in her deposition and explained why she found the study not to have any impact on her decision to prescribe Plavix to Plaintiff. Accordingly, because Plaintiff fails to raise a genuine issue of material fact on causation, her failure to warn claims (Counts I and III) are

history of ulcers, which condition occurred more than ten years before her prescription. As such, it is a tenuous comparison between Plaintiff's situation and the study's results from patients with active bleeding ulcers.

dismissed, and Defendants' motion for summary judgment is granted in this regard.

III. Remainder of Plaintiff's Claims

In her Complaint, Plaintiff also asserts claims of design defect (Count I), manufacturing defect (Count II) and negligence (IV).⁶ As to the negligence claim, Plaintiff does not dispute that her allegations of negligence merely restate the averments made on her failure to warn claim. Thus, the negligence claim is dismissed for the same reasons why Plaintiff failed to sustain her failure to warn claim. See *Motus*, 196 F. Supp. 2d at 999 (granting summary judgment on a failure to warn claim and then dismissing the negligence claim because that claim was premised on the same allegations that the defendants failed to adequately warn of the risk of a drug).

Similarly, Plaintiff's manufacturing defect claim is also dismissed, because Plaintiff presents no evidence that the

⁶ Thorpe's claims are part of a multi-plaintiff complaint, wherein the Complaint asserts additional claims for loss of consortium and wrongful death. As to this particular plaintiff, because there is no allegation that Thorpe is deceased, the wrongful death claim clearly does not apply, here. Additionally, there is no indication that Thorpe is pursuing a loss of consortium claim. Even if she were, because all of her causes of action are dismissed on this summary judgment motion, the lost consortium claim would correspondingly be dismissed. See *Thomsen v. Sacramento Metro. Fire Dist.*, No. 09-01108, 2009 U.S. Dist. LEXIS 97242, at *39 (E.D. Cal. Oct. 20, 2009)(finding that under California law, a claim for loss of consortium does not stand on its own, but is recognized as a derivative of other injuries not an injury in and of itself).

Plavix she used differed from the manufacturer's intended result, which is a required element of that claim. *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 429 (1978) ("a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line."). Therefore, Plaintiff's manufacturing defect claim is dismissed.

Finally, summary judgment as to Plaintiff's design defect claim is appropriate. I note that in her briefing, while Plaintiff opposes the dismissal of this particular claim, she, nevertheless, does not make any substantive argument as to why her design defect claim should proceed if her failure to warn claim is dismissed. Indeed, California courts have carved out an "exception" to strict manufacturing liability when it comes to prescription drugs. *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1392 (1994). In *Brown v. Superior Court*, the California Supreme Court concluded that "a drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability" but, rather, the "appropriate test for determining responsibility is the test stated in comment k [to section 402A of the Restatement Second of Torts ("Comment k")]." 44 Cal. 3d 1049, 1061 (1988) (basing its conclusion, in part, on "the public interest in the

development, availability, and reasonable price of drugs"). In that regard, *Brown* established that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." 44 Cal. 3d at 1069. Despite the exception for prescription drugs set forth in *Brown*, the Court made clear that drug manufacturers remain subject to liability for manufacturing defects, negligence, and for failure to warn of known or reasonably knowable side effects. *Id.* at 1069 n.12.

Here, under California law, Plaintiff cannot pursue a design defect claim when her failure to warn claim has been dismissed, and she has failed to demonstrate that Plavix was not accompanied by a proper warning. As I stated earlier, Plaintiff, in her opposition, has not cited to any evidence, or made any arguments, as to why summary judgment should be denied on her design defect claim, effectively abandoning such a claim in that respect. See, e.g., *Angle v. United States*, No. 12-2495, 2012 U.S. Dist. LEXIS 181686, at *8-9 (D.N.J. Dec. 21, 2012); *Oticon, Inc. v. Sebotek Hearing Sys., LLC*, 865 F. Supp. 2d 501, 508 n.5 (D.N.J. 2011). Moreover, the Court, independently, cannot find any basis to deny summary judgment on this claim, and therefore, it is dismissed.

CONCLUSION

For the reasons expressed above, Defendants' motion for summary judgment is **GRANTED**. Plaintiff's Complaint is, therefore, dismissed.

DATED: October 26, 2017

/s/ Freda L. Wolfson
Freda L. Wolfson
United States District Judge